

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Application Number	10/829,618
Filing Date	4/20/2004
Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

U.S. PATENT DOCUMENTS

Exam. Initial	No.	Document No.	Issue/Publication Date	Applicant(s)
	1.	4615697	10/7/1986	Robinson
	2.	4919937	4/24/1990	Mauvais-Jarvis et al.
	3.	3164520	1/5/1965	Huber
	4.	4496455	1/29/1985	Linder et al.
	5.	5769274	6/23/1998	Behar
	6.	5926953	7/27/1999	Behar

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Exam. Initial	No.	Document No.	Publication Date	Country
	7.	WO9637201	11/28/1996	PCT
	8.	WO9830198	7/16/1998	PCT

OTHER DOCUMENTS (Non-patent literature)

Exam. Initial	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	9.	"ALZA introduces TESTODERM TTS for testosterone deficiency - survey finds key role of testosterone unknown to most men." Alza. March 11, 1998. http://www.alza.com/print/pr_957321395 (accessed 11/15/2004).

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	11.	"Cellegy Pharmaceuticals Initiates Phase III Clinical Trial Using Transdermal Testosterone Gel." PR Newswire. March 29, 2000.
	12.	"Cellegy Pharmaceuticals Market Opportunities." Cellegy Pharmaceuticals. http://www.cellegy.com/products/market.html (accessed 11/19/1998).
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	14.	"Erratum." The Lancet. 354(9178): 602 (1999).
	15.	"New Testosterone Replacement Gel, AndroGel®, Available Nationwide to Treat Men with Low Testosterone." AndroGel.com. http://www.androgel.com/media/press_release000614.htm (6/14/2000).
	16.	"Unimed Pharmaceuticals Completes Clinical Trial Enrollment for First Topical Testosterone Replacement Gel." Press Release. May 28, 1998.
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	22.	Kim et al. "Preparation and evaluation of Eudragit gels. v. rectal gel preparations for sustained release and avoidance of first-pass metabolism of lidocaine." Chem. Pharm. Bull. 50(10): 2800-2804 (1992).
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	27.	O'Carroll et al. "Androgens, behaviour and nocturnal erection in hypogonadal men: the effects of varying the replacement dose." Clin. Endocrinol. 23: 527-538 (1985).
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	32.	Thompson, ed. "The Concise Oxford Dictionary." 9th ed. Oxford: Oxford University Press, 1995, pp. 1014.
	33.	Tremblay et al. "Plasma concentrations of free and non-TeBG bound testosterone in women on oral contraceptives." Contraception. 10(6): 599-605 (1974). [Abstract only]
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OFFICE ACTIONS AND RESPONSES IN CO-PENDING U.S. PATENT APPLICATIONS

Exam Initial	No.	Application Serial No.	Date of Office Action or Response
	35.	10/829618	12-30-2010 Final Rejection

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	37.	5952000	7/21/1997	Venkateshwaran (previously cited in IDS filed 11/12/2010(2))
	38.	5686112	11/11/1997	Liedtke (previously cited in IDS filed 11/12/2010(2))
	39.	5788983	8/4/1998	Chien et al. (previously cited in IDS filed 11/12/2010(1))
	40.	5942545	8/24/1999	Samour et al. (previously cited in IDS filed 11/12/2010(2))
	41.	6319913	11/20/2001	Mak et al. (previously cited in IDS filed 11/12/2010(1))

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	66.	Osborne et al., Skin Penetration Enhancers Cited in Technical Literature, Pharmaceutical Technology. pp. 58, 60, 62, 64 and 66, November 1997 (previously cited in IDS filed 11/12/2010(2))
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	87.	Noveon, Formulating Hydroalcoholic Gels with Carbopol Polymers, Noveon TDS-255, December 1999 (previously cited in IDS filed 11/12/2010(2))
	88.	WINTERS, Current Status of Testosterone Replacement Therapy in Men, Arch. Fam. Med., Vol. 8, pp. 257-263 (1999) (previously cited in IDS filed 11/12/2010(2))
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	91.	Kaufman, "Hormone Gel Stirs Debate," The Washington Post, p. A01 (May 27, 2000)
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	100.	Noveon Product Specification: Carbopol 674 Polymer (November 2001)
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Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	134.	Noveon Product Specification: Carbopol 974P NF Polymer (January 2003)
	135.	Noveon Product Specification: Carbopol 1342 NF (January 2003)
	136.	Noveon TDS-297: Carbopol Ultrez 21 Polymer, Technical Data Sheet (February 2003)
	137.	Noveon Product Specification: Carbopol Ultrez 10 NF Polymer (May 2003)
	138.	Greider, "Experts Divided on Value of Testosterone Therapy for Men," AARP Bulletin Online (July-August 2003)
	139.	Noveon Product Specification: Carbopol EZ-2 Polymer (August 2003)
	140.	Noveon Product Specification: Carbopol EZ-3 Polymer (August 2003)
	141.	Noveon Product Specification: Carbopol Ultrez 21 Polymer (September 2003)
	142.	Press Release, "The Endocrine Society Responds to the Institute of Medicine Report on Testosterone Therapy for Older Men" (November 17, 2003)
	143.	Basaria et al., "New Modalities of Transdermal Testosterone Replacement," Treat Endocrinol, 2(1): 1-9 (2003); Abstract
	144.	Hameed, A. et al. Delivery of testosterone replacement therapy. Curr Opin in Invest Drugs 2003. 4(1):1213-1219 (previously cited in IDS filed 11/12/2010(2))
	145.	Handbook of Pharmaceuticals Excipients, Fourth Edition, pp. 89-92, 95-100, 289-296, 309-313, 543-545, 566-567, 654-656, 691-693 (2003)
	146.	Rhoden et al., "Risks of Testosterone-Replacement Therapy and Recommendations for Monitoring," N Engl J Med 350:5, 482-492 (2004)
	147.	Testosterone and Aging: Clinical Research Directions, Institute of Medicine of the National Academies (Liverman and Blazer, eds.)(2004)

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Application Number	10/829,618
Filing Date	4/20/2004
Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	148.	Chan, T.C. Percutaneous penetration enhancers: An update. Predgs of 9th Biennial Intl Conf of Perspectives in Percutaneous Penetration, La Grand Motte, France, April 13, 2004; published January 2005 (previously cited in IDS filed 11/12/2010(2))
	149.	Press Release, Cellegy Announces Settlement of PDI Litigation (April 12, 2005)
	150.	Androgen Deficiency in Aging Men Questionnaire, Saint Louis University, available at www.slu.edu/adam (retrieved 5/23/2005)
	151.	Medline Plus, Drug Information: Testosterone Topical, available at www.nlm.nih.gov/medlineplus/druginfo/medmaster/a605020.html (retrieved 6/3/2005)
	152.	Random House Webster's Unabridged Dictionary, 2d Edition, "pharmaceutical": p. 1451 and "drug": p. 600 (2005)
	153.	Random House Webster's Unabridged Dictionary, 2d Edition, "ethanol": p. 665 and "alcohol": p. 49 (2005)

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Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

LITIGATION DOCUMENTS

Unimed Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc., Docket No. 1:03-cv-02501-TWT (N.D. Ga. 2003)

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	154.	Docket Report for Unimed Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc. (retrieved from PACER 1/4/2011)
	155.	Complaint by Unimed Pharmaceuticals filed 8/21/2003
	156.	Plaintiff Unimed Pharmaceutical, Inc.'s Rule 7.1 Corporate Ownership Disclosure Statement filed 8/21/2003
	157.	First Amended Complaint by Unimed Pharmaceuticals filed 8/22/2003
	158.	Answer and Counterclaim by Watson Pharmaceuticals filed 10/27/2003
	159.	Answer to Counterclaim by Unimed Pharmaceuticals filed 11/17/2003
	160.	Joint Preliminary Report and Discovery Plan filed 11/26/2003
	161.	Certificate of Interested Persons filed 11/26/2003
	162.	Letter by Watson Pharmaceuticals directed to Judge Thrash as a Response to the Letter Motion to Compel filed 10/21/2004
	163.	Watson Pharmaceutical's Motion to Issue Letter of Request for International Judicial Assistance dated 12/2/2004
	164.	Request for International Judicial Assistance by Judge Thrash dated 12/22/2004
	165.	Unimed Pharmaceuticals, Inc.'s Objections to Watson Pharmaceuticals, Inc.'s Notice of Depositions filed 3/17/2005
	166.	Watson's Principal Claim Construction Brief filed 7/25/2005

Examiner Signature	Date Considered
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Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	167.	Plaintiff's Memorandum on Claim Construction (Redacted Version) filed 7/25/2005
	168.	Watson's Reply to Plaintiff's Principal Claim-Construction Brief dated 8/12/2005
	169.	Plaintiff's Opposition Brief on Claim Construction (Redacted Version) dated 8/12/2005
	170.	Watson's Motion to Strike Section VI of Plaintiffs' Memorandum on Claim Construction filed 8/12/2005
	171.	Plaintiff's Response to Watson's Motion to Strike Section VI of Plaintiff's Claim Construction Memorandum filed 8/26/2005
	172.	Watson's Reply in Support of Its Motion to Strike Section VI of Plaintiffs' Claim-Construction Memorandum filed 9/9/2005
	173.	Defendant Watson Pharmaceuticals, Inc.'s Motion for Partial Summary Judgment filed 9/9/2005
	174.	Plaintiffs' Consolidated Memorandum of Law in Opposition to Defendants' Motions for Partial Summary Judgment filed 10/17/2005
	175.	Unimed Pharmaceuticals, Inc.'s Statement of Additional Facts which are Material and Present A Genuine Issue for Trial filed 10/17/2005
	176.	Plaintiffs' Consolidated Response to Defendants Watson's and Paddock's Statement of Material Facts as to Which There are No Genuine Issues to be Tried filed 10/17/2005
	177.	Watson's Response to Plaintiffs' Statement of Additional Facts which are Material and Present a Genuine Issue for Trial filed 11/11/2005
	178.	Watson's Reply to Plaintiffs' Consolidated Opposition to Defendants' Motions for Partial Summary Judgment filed 11/11/2005

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Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	179.	Defendant Watson Pharmaceuticals, Inc.'s Motion for Partial Summary Judgment of Invalidity of Claims 1-30 for Failure to Comply with the Written Description Requirement filed 11/23/2005
	180.	Plaintiffs' Consolidated Memorandum of Law in Opposition to Defendants' Motions for Partial Summary Judgment of Invalidity of Claims 1-30 filed 12/19/2005
	181.	Unimed Pharmaceuticals, Inc.'s Statement of Additional Facts which are Material and Present a Genuine Issue for Trial filed 12/19/2005
	182.	Plaintiffs' Consolidated Response to Defendants Watson's and Paddock's Statements of Material Facts as to Which There are No Genuine Issues to be Tried Regarding Invalidity of Claims 1-30 of the '894 Patent Lacking a Written Description under 35 U.S.C. § 112 filed 12/19/2005
	183.	Watson's Reply Memorandum of Law in Support of its Motion for Partial Summary Judgment of Invalidity of Claims 1-30 for Failure to Comply with the Written Description Requirement filed 1/19/2006
	184.	Watson's Response to Plaintiff's Statement of Additional Facts which are Material and Present a Genuine Issue for Trial filed 1/19/2006

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Substitute for form 1449/P10

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/829,618
Filing Date	4/20/2004
Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

LITIGATION DOCUMENTS

Unimed Pharmaceuticals, Inc. v. Paddock Laboratories, Inc., Docket No. 1:03-cv-02503-TWT (N.D. Ga. 2003)

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	185.	Docket Report for Unimed Pharmaceuticals, Inc. v. Paddock Laboratories, Inc. (retrieved from PACER 1/4/2011)
	186.	Complaint by Unimed Pharmaceuticals dated 8/21/2003
	187.	Plaintiff Unimed Pharmaceuticals, Inc.'s Rule 7.1 Corporate Ownership Disclosure Statement filed 8/21/2003
	188.	First Amended Complaint by Unimed Pharmaceuticals filed 8/22/2003
	189.	Answer and Counterclaim by Paddock Laboratories filed 10/22/2003
	190.	Answer to Counterclaims by Unimed Pharmaceuticals filed 11/12/2003
	191.	Certificate of Interested Persons filed 11/21/2003
	192.	Joint Preliminary Report and Discovery Plan filed 11/21/2003
	193.	Defendant's Rule 26 Disclosures filed 12/12/2003
	194.	Paddock's Motion to Issue Letters of Request for International Judicial Assistance filed 12/1/2004
	195.	Request for International Judicial Assistance by Judge Thrash dated 12/9/2004
	196.	Unimed Pharmaceuticals, Inc.'s Objections to Paddock Laboratories, Inc.'s Notices of Depositions Under Rule 30(b)(6) dated 3/17/2005
	197.	Paddock's Opening Claim Construction Brief (Redacted Version) filed 7/25/2005

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Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	198.	Paddock's Opposition Claim Construction Brief filed 8/12/2005
	199.	Defendant Paddock Laboratories, Inc.'s Motion for Partial Summary Judgment filed 9/27/2005
	200.	Memorandum in Support of Paddock's Motion for Partial Summary Judgment of Invalidity of Claims 1-30 of the '894 Patent as Lacking a Written Description as Required by 35 U.S.C. § 112, First Paragraph with Respect to the Claimed Ranges of Sodium Hydroxide filed 10/18/2005
	201.	Paddock's Reply Memorandum in Further Support of its Motion for Partial Summary Judgment as to the Inapplicability and Invalidity of the Certificate of Correction filed 11/11/2005
	202.	Paddock's Response to Plaintiffs' Statement of Additional Facts which are Material and Present a Genuine Issue for Trial filed 11/11/2005
	203.	Defendant Paddock Laboratories, Inc.'s Motion in Limine to Exclude Unimed's Argument and Expert Testimony on the Basis of, and Support in the Specification for, the Sodium Hydroxide Ranges Recited in Certain Claims of the '894 Patent filed 11/28/2005
	204.	Plaintiffs' Memorandum of Law in Opposition to Paddock's Motion in Limine to Exclude Plaintiffs' Argument and Expert Testimony on the Sodium Hydroxide Ranges filed 1/13/2006
	205.	Paddock's Reply memorandum in Further Support of its Motion for Partial Summary Judgment as to the Invalidity of Claims 1-30 under 35 U.S.C. § 112 filed 1/19/2006
	206.	Paddock's Response to Unimed's Statement of Additional Facts which are Material and Present a Genuine Issue for Trial with Respect to Paddock's motion of Summary Judgment that Claims 1-30 of the '894 Patent are Invalid under 35 U.S.C. § 112 filed 1/19/2006
	207.	Paddock's Reply Brief in Further Support of its Motion In Limine to Exclude

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Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
		Unimed's Argument and Expert Testimony on the Basis of, and Support in the Specification for, the Sodium Hydroxide Ranges Recited in Certain Claims of the '894 Patent filed 1/31/2006
	208.	Consent Judgment and Order of Permanent Injunction dated 9/15/2006

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Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

LITIGATION DOCUMENTS - In Re Androgel Antitrust Litigation (No. II), Docket No. 1:09-md-02084-TWT (N.D. Ga. 2009)

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	209.	Docket Report for In re Androgel Antitrust Litigation (No. II) (retrieved from PACER 1/5/2011)
	210.	Complaint, Meijer, Inc. v. Unimed Pharmaceuticals, Inc. (originally filed in C.D. Cal. on 2/2/2009)
	211.	Complaint, Louisiana Wholesale Drug Co. v. Unimed Pharmaceuticals, Inc. (originally filed in C.D. Cal. on 2/3/2009)
	212.	Complaint, Rochester Drug Co-operative, Inc. v. Unimed Pharmaceuticals, Inc. (originally filed in C.D. Cal. on 2/3/2009)
	213.	First Amended Complaint, Federal Trade Commission v. Watson Pharmaceuticals, Inc., Case No. CV 09-598 MRP (originally filed in C.D. Cal. on 2/12/2009)
	214.	Complaint, Stephen L. LaFrance Pharmacy, Inc. v. Unimed Pharmaceuticals, Inc. (originally filed in D.N.J. on 3/31/2009)
	215.	Complaint, Fraternal Order of Police v. Unimed Pharmaceuticals, Inc. (originally filed in D.N.J. on 4/17/2009)
	216.	Complaint, Scurto v. Unimed Pharmaceuticals, Inc. (originally filed in D.N.J. on 4/21/2009)
	217.	Complaint, United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund v. Unimed Pharmaceuticals, Inc. (originally filed in D. Minn. 2009)
	218.	Complaint, Rite Aid Corp. v. Unimed Pharmaceuticals, Inc. (originally filed in M.D. Penn. on 6/17/2009)
	219.	Complaint, Walgreen Co. v. Unimed Pharmaceuticals, Inc. (originally filed in M.D.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Filing Date	4/20/2004
Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
		Penn. on 6/29/2009)
	220.	Complaint, Jabo's Pharmacy, Inc. v. Solvay Pharmaceuticals, Inc. (originally filed in Circuit Court for Cocke County, Tennessee on 10/30/2009)
	221.	Complaint, Supervalu Inc. v. Unimed Pharmaceuticals, Inc. (originally filed in N.D. Ga. on 4/7/2010)
	222.	Complaint, LeGrand v. Unimed Pharmaceuticals, Inc. (originally filed in N.D. Ga. on 9/10/2010)
	223.	Order Granting in Part and Denying in Part Defendant's Motions to Dismiss dated 2/22/2010
	224.	Amended Class Action Complaint and Jury Demand, Fraternal Order of Police v. Unimed Pharmaceuticals, Inc., Case No. 09-md-2084-TWT (filed 3/5/2010)

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